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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,129	06/25/2001	Ryuji Ueno	210227US0XPC	2213

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EXAMINER

CHISM, BILLY D

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 09/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/869,129

Applicant(s)

UENO, RYUJI

Examiner

B. Dell Chism

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,4,6-9 and 11-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,4,6-9 and 11-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to Paper No. 7, filed 11 June 2003.

Withdrawal of Objections and Rejections

The rejections and/or objections made in the prior office action filed 11 March 2003, which are not explicitly stated below, in original or modified form are withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Applicants' arguments filed 11 June 2003 will be addressed to the extent that they pertain to the present grounds of rejection.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. (Maintained) Claims 3-4 and 6-8 remain rejected under 35 U.S.C. 102(b) as being anticipated by Ryffel *et al.* Ryffel *et al.* teach FK506 for inhibiting IL-2R transcription, although the use of FK506 was for inhibition of IL-2R, the agent is within the metes and bounds of the agent claimed in and by the structure of claim 3. Consequently, the phrase “for treating retinopathy” is a statement of intended use, not a limitation to a product as claimed. The phrase

Art Unit: 1654

“for treating retinopathy” is the preamble of the claim, which states the intended use of the composition. If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states the purpose or intended use, then the preamble is not considered a limitation. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) (“where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation”). If a prior art structure is capable of performing the intended use, as recited in the preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) (MPEP §2111.02, See also MPEP §2112-211.02).

3. **(Necessitated By Amendment)** Claims 3-4 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Ishioka *et al.* 1994. Ishioka *et al.* teach a method of using FK506 for treatment of uveitis in Behcet’s syndrome patients, wherein uveitis is a type of retinopathy. Although the use of FK506 was for treatment of uveitis, the agent is within the metes and bounds of the agent claimed in and by the structure of claim 3. Consequently, the phrase “for treating retinopathy” is a statement of intended use, not a limitation to a product as claimed. The phrase “for treating retinopathy” is the preamble of the claim, which states the intended use of the composition. If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states the purpose or intended use, then the preamble is not considered a limitation. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). See also *Rowe v. Dror*, 112 F.3d 473, 478, 42

Art Unit: 1654

USPQ2d 1550, 1553 (Fed. Cir. 1997) (“where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation”). If a prior art structure is capable of performing the intended use, as recited in the preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) (MPEP §2111.02, See also MPEP §2112-211.02).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **(Necessitated by Amendment)** Claims 3-4, 6-9, and 11-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishioka *et al.* in combination with Stuchlik *et al.* (WO 99/34830).

Ishioka *et al.* teaches the use of immunosuppressive agents, i.e., FK506, of the claimed structures in treating uveitis, however, Ishioka *et al.* does not teach local application to the eye.

Stuchlik *et al.* teaches use of immunosuppressants (macrolide lactones, i.e., tacrolimus (FK506)) for local topical treatment to the eye as well as various types of carriers and/or delivery compounds for such use, wherein Stuchlik *et al.* teach methods of increasing penetration of such compounds across the cornea, via topical application, into the internal tissues of the eye (page 4).

Art Unit: 1654

Stuchlik *et al.* also teach applicability of the topicals in preparations as “characterized by high penetration of immunosuppressive agents into ocular tissues and in a very good tolerability.”

Although Stuchlik *et al.* do not teach a method of using a composition comprising the specifically claimed concentration of the compounds for the local administration, absent some evidence to the contrary, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have optimized the concentration for local administration. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235.

Furthermore, it would be obvious to one of skill in the art that the penetration of a macrolide lactone, i.e., tacrolimus, into the internal tissues, as disclosed by Stuchlik *et al.*, of the eye would encompass the retina and the tissues associated. Thus, Stuchlik *et al.* renders obvious the method of applying the presently claimed compound locally to the eye for treatment of retinopathy, which is damage to the internal tissues of the eye as is described in Stuchlik *et al.*

Thus, absent evidence to the contrary, together these two prior art references render the presently claimed methods *prima facie* obvious, wherein one of ordinary skill in the art at the time of the present invention would have motivated to optimize dosages and concentrations, and delivery techniques using methods known in the art.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1654

7. **(Necessitated by Amendments)** Claims 15-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15-16 are indefinite for the recitation of the term "is comprises..." wherein the "is" should be deleted. Furthermore, each claim 15-16 is indefinite wherein each claim recites "w/v%". The term is unclear and should be presented in written form, i.e., --5 % weight per volume--.

Conclusions

8. No claims are allowed. Applicants' amendments necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

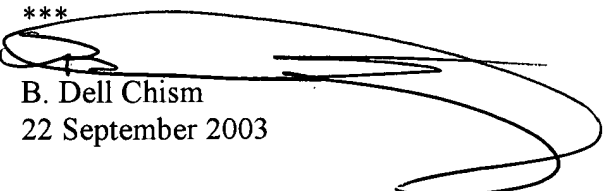
Art Unit: 1654

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 703-306-5815. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

B. Dell Chism
22 September 2003



Brenda Brumback
BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600